PHARMACY IV ADMIXTURE

Pharmacy 483

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- Pharmacist is responsible for ensuring that compounded sterile preparations are properly prepared, labeled, stored, dispensed and delivered.
  - USP
  - ASHP
  - NABP
  - JCAHO

Centralized IV Admixture Service

- Economical
  - Batch preparation
  - Reduce personnel time
- Enhanced safety with standardized solutions.
- Double check process on all prepared solutions.
- Cleaner, more controlled environment.

USP-797

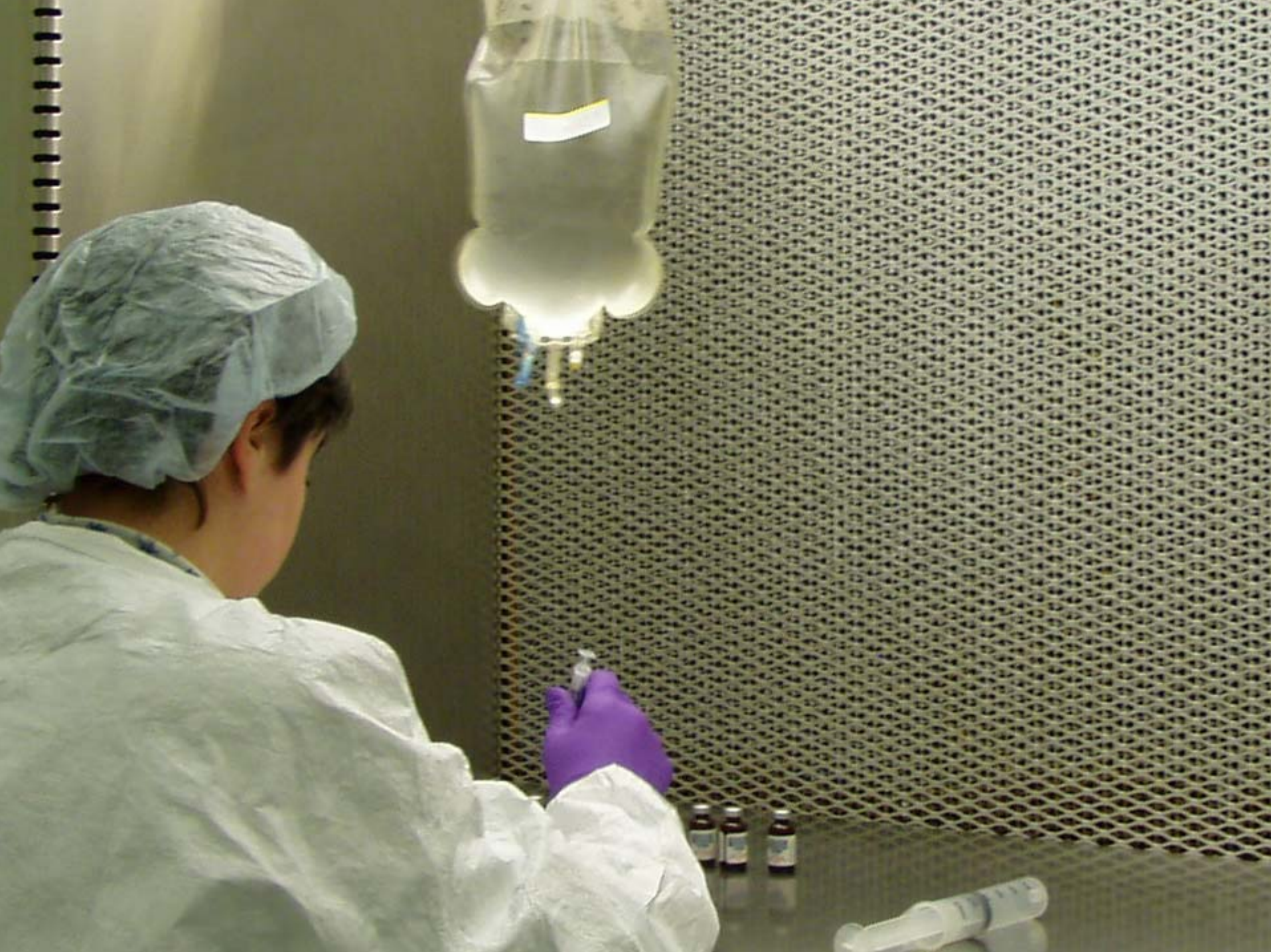
- New standards effective Jan 2004
- Standards will be enforced by Boards of Pharmacy.
- Sterile product preparations are categorized as high, medium or low risk preparations based on the potential for microbial, chemical and physical contamination.

Buffer Room

- Must be ISO Class 7 (Class 10,000)
- Prepared in a ISO Class 5 (Class 100) laminar airflow workbench
- Positive pressure room with HEPA filtered air.
- Access is restricted in Buffer area.

ISO Class 7

- Also referred to as a Class 10,000 environment.
- Air particle count does not exceed 10,000 particles 0.5 microns or larger per cubic foot of air.



Buffer Rooms

- Walls, floors, ceiling should be smooth, no cracks and crevices.
- Ceilings should be sealed.
- Floors coved.
- No sinks in Buffer area.
- Only non-shedding paper products in area.

Ante-Room or Ante-Area

- Gowning and hand-washing.
- No food or beverages.
- No carts moving back and forth from buffer zone to ante-area.
- Wipe down of products before introducing into the buffer area.

Laminar Flow Hoods

- Horizontal
- Vertical
- Barrier Isolators
- Certified every 6 mo.
- ISO Class 5 (Class 100) environment.

Gowning

- Remove make-up, jewelry.
- Scrub hands and arms to elbow.
- Non-shedding gown, knee length with a zip or snap front.
- Shoe covers, hair covers, face mask and gloves.

Risk Classification

Low-Risk Compounding	Simple admixtures using closed system transfer methods.
Medium-Risk Compounding	Admixtures using multiple additives or batch preparations.
High-Risk Compounding	Non-sterile ingredients or open-system transfers.

Beyond-Use Dating

- Storage period before administration.
- When compounded sterile products are stored for prolonged periods of time there is potential for microbial growth and pyrogen formation.
  - Chemical stability
  - Microbial sterility

Beyond-Use Dating

Risk Level	Room Temp	Refrigeration	Freezer
Low	48 hrs	14 days	45 days
Medium	30 hrs	9 days	45 days
High	24 hrs	3 days	45 days

Personnel

- Documented education, training and competency.
  - Didactic training.
  - Competency tests.
  - Return demonstration/observation.
  - Media-fill testing of aseptic manipulative skills.

Media-fill test kit

Media-fill challenge testing

- –Sterile bacterial culture medium transferred via a variety of aseptic manipulations
- –Test should represent the most challenging products made for a particular risk level
- –Products are monitored for microbial growth, indicated by visual turbidity, for 14 days
- –Done annually and for new employees

Environmental Controls and Testing

- Routine cleaning schedule.
- Laminar flow hood certification every 6 months.
- Particle-count testing.
- Electric air samplers or agar settling plates.


THIS EQUIPMENT HAS BEEN CERTIFIED
BY CSA WITH REGARDS TO SAFETY
FROM SHOCK AND FIRE HAZARD
CET EQUIPMENT A ETE CERTIFIE PAR
L'ANCOR (CSA) POUR SA SECURITE DU
POINT DE VUE CHOC ELECTRIQUE ET
RISQUE D'INCENDIE
BioGARD Hood
he BAKER COMPANY, inc.

Total Parenteral Nutrition

- Multiple ingredients (1-3 liters).
- Standard Operating Procedures.
- Automated Compounders
  - Improve accuracy and efficiency.
  - Accuracy verified by weight, volume.

Hazardous Drugs

- NIOSH (National Institute for Occupational Safety and Health) Guidelines.
- Vertical flow hood vented to the outside to protect operator.
- Pharmacy attaches tubing to reduce RN exposure.
- Negative pressure room.
- Separate storage/Receiving procedures.

Resources

- United States Pharmacopeia (USP) web site: www.usp.org
- American Society of Health-System Pharmacists (ASHP) web site: www.ashp.org
- Kastango ES, Bradshaw BD. USP chapter 797: Establishing a practice standard for compounding sterile preparations in pharmacy. Am J Health-Syst Pharm. 2004; 61:1928-1938.